JAN - 6 2012

510(K) SUMMARY

Submitter Information

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Date Prepared June 6, 2011

Device Name

Trade/Proprietary Name: SonoTT FlowLab®

Common/Usual Name: Blood Flow Meter

Classification Name: Flowmeter, Blood, Cardiovascular

CFR § 870.2100 Product Code

DPW

Classification: Class II

Predicate Device Name

Trade name: MediStim VeriQ VQ1001- VQ4122

SonoTT Ultrasonic Flowcomputer

These devices are the same in terms of Intended use/Indication, clinical applications, type of construction, measurement technology, sensor types, energy source and emitted energy, anatomical sites and material/biocompatibility issues.

Device Description

The SonoTT FlowLab® is used for the volumetric measurement of liquid flowing through tubing systems (in combination with the SonoTT Clamp-On Transducer), to measure blood volume flow (in combination with the SonoTT Vascular Probe) and flow velocity in arteries and veins (in combination with the SonoTT Pulse Wave

Doppler Probe). The measurement principle is the ultrasound transit-time and Doppler method.

Substantial Equivalence

	Medi-Stim VeriQ VQ1001- VQ4122	SonoTT Ultrasonic Flowcomputer	SonoTT *Flow*Lab®
Indications for use	The Medi-Stim VeriQ System is an intraoperative diagnostic system that utilizes ultrasonography to guide surgeons to successfully plan and accomplish surgical interventions. The clinical indications for the device are: 1) Accurate transit time blood volume and Doppler velocity flow measurements during cardiovascular-, vascular-, transplantation- and neuro-surgery 2) Simultaneous measurements of blood pressure, vascular resistance, interfaced physiological signals and other derived parameters during these procedures. 3) Detection of normal	The Sono TT Ultrasonic Flowcomputer is indicated for the volumetric measurement of liquid flowing through tubing systems (with Clamp-On Transducer). The measurement principle is the ultrasound transit-time method.The Flowcomputer is designed for continuous operation in intensive care units and operating rooms. For the patient's safety the device is to be operated only by qualified medically-trained personnel. The medical use of the device is appropriate to procedures such as the following: 1) Extracorporeal flow measurement on tubings with Clamp-On Transducer during interventions like Cardio-pulmonary bypass, membrane-oxygenation, hemodialysis, hemofiltration, plasmapheresis, perfusion, infusion, transfusion	The SonoTT FlowLab® with the accessories is a system to measure the flow rate of liquids (e.g. blood) with the ultrasonic transit-time and velocity patterns of blood with Doppler method. It supports the planning, implementation, efficiency control and documentation of interventions carried out in the area of cardiovascular, vascular and, transplantation, or the monitoring of extracorporeal circulatory systems. The following medical applications are supported: 1) Intraoperative blood flow measurement with the SonoTT Vascular Probe to assist surgeons at surgical interventions 2) Measurement of flow direction and velocities of blood in vessels using the SonoTT Pulse Wave Doppler Probe to assist the surgeon in the non-invasive assessment of vascular changes. 3) Extracorporeal flow measurement in continuous operation on tube systems in combination with the SonoTT Clamp-On Transducer in intensive

	and abnormal blood volume and Doppler velocity flow patterns during these procedures. 4) Provides guidance to prepare surgical plans at the initiation of surgery and to support the successful accomplishment of surgery including detection and location of vessels during surgical procedures. 5) Detection and quantification of the degree of stenosis in arteries by using the Doppler velocity profile.		care units and operating theatres The following actions can be performed simultaneously when these measurements are in progress: 4) Pressure measurement in combination with a standard blood pressure transducer 5) Secondary displays of additional physiological analogue signals and corresponding derived parameters The SonoTT Vascular Probe is intended for transient use only with continuous contact with patient of less than 60 minutes. For the patient's safety they must be operated by qualified medical personnel.
Patient group	Adult and pediatric Not intended for any kind of fetal applications. acc. operator manual	No restrictions acc. operator manual	Adult and pediatric Not intended for examination of foetuses (prenatal) and neonates (foetal) .
Ultrasound modalities	Transit-time, PW Doppler	Transit time, PW Doppler	Transit time, PW Doppler
Measurement Probes	Vessel transducer, Doppler Probe	Clamp-on Sensor	Vessel transducer, Doppler Probe, Clamp-on Sensor
Other inputs	Blood pressure, ECG, Auxiliary inputs	Blood pressure, Auxiliary inputs	Blood pressure, ECG, Auxiliary inputs

The proposed device is substantial equivalent to the predicate devices with respect to intended use, patient population, measurement and sensor technology and auxiliary channels. Therefore it meets the requirements for section 510(k) substantial equivalence and is as safe, as effective, and performs as well as the predicate devices

Test Data

The **SonoTT FlowLab®** and the accessories were subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

1. Electrical Safety Testing
2. EMC Testing
3. Ultrasonic acoustic output testing
4. Alarm testing
5. Software Validation
6. Mechanical Stability Testing
7. Packaging Testing
8. Biocompatibility evaluation of Vascular Probe and Pulse Wave Doppler Probe
9. Sterility evaluation of Vascular Probe
10. Usability Validation

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a **Blood Flow Meter**.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN - 6 2012

em-tec GmbH
c/o Mr. Olaf Teichert
TÜV SÜD America, Inc.
1775 Old Highway 8 NW, Ste 104
New Brighton, MN 55112-1891

Re: K111730
Trade/Device Name: SonoTT FlowLab® Flowmeter
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II (two)
Product Codes: DPW, ITX
Dated: December 28, 2011
Received: December 30, 2011

Dear Mr. Teichert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Submission Section D	SonoTT FlowLab		em-tec MEDICAL TECHNOLOGY
Indications for Use	FL-FDIU-1.1.doc	05/26/11	

Indications for Use

510(k) Number (if known): K111730

Device Name: SonoTT FlowLab

Indications for Use

The SonoTT FlowLab® with the accessories is a system to measure the flow rate of liquids (e.g. blood) with the ultrasonic transit-time and velocity patterns of blood with Doppler method. It supports the planning, implementation, efficiency control and documentation of interventions carried out in the area of cardiovascular, vascular and, transplantation, or the monitoring of extracorporeal circulatory systems.

The following medical applications are supported:

- Intraoperative blood flow measurement with the SonoTT Vascular Probe to assist surgeons at surgical interventions
- Measurement of flow direction and velocities of blood in vessels using the SonoTT Pulse Wave Doppler Probe to assist the surgeon in the non-invasive assessment of vascular changes.
- Extracorporeal flow measurement in continuous operation on tube systems in combination with the SonoTT Clamp-On Transducer in intensive care units and operating theatres

The following actions can be performed simultaneously when these measurements are in progress:

- Pressure measurement in combination with a standard blood pressure transducer
- Secondary displays of additional physiological analogue signals and corresponding derived parameters

The SonoTT Vascular Probe is intended for transient use only with continuous contact with patient of less than 60 minutes.

For the patient's safety they must be operated by qualified medical personnel.

Contraindication

The SonoTT FlowLab® and the accessories Vascular Probe, Clamp-On Transducer and Pulse Wave Doppler Probe were exclusively designed for the described intended use.

The device is expressly not intended for the following:

- The Vascular Probe for measurements on stented areas of blood vessels.
- Examination of foetuses (prenatal) and neonates (foetal) with the Doppler Probe
- Doppler measurements of eyes (ophthalmology), in gynaecology or in obstetrics
- Monitoring of vital physiological parameters
- Measurements at human arteries or veins using the Clamp-On Transducer

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510(k) Submission Section D	SonoTT FlowLab		em-tec MEDICAL TECHNOLOGY
Indications for Use	FL-FDIU-1.1.doc	05/26/11	

Prescription Use Yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111730